

**Arnold, Amy**

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**From:** Osborne, Kevin (PMMC Legal)  
**Sent:** Wednesday, October 30, 2002 4:34 PM  
**To:** Arnold, Amy  
**Subject:** RE: FW: Lab data specifications

yes.

Re confidentiality, there's a PM USA-MDS conf. obligations and, presumably, a Cov.-E-trials conf. agmt. The latter should be verified.

-----Original Message-----

**From:** Arnold, Amy  
**Sent:** Wednesday, October 30, 2002 4:07 PM  
**To:** Osborne, Kevin (PMMC Legal)  
**Subject:** RE: FW: Lab data specifications

Kevin:

Exhibit A to P.A. #2 states that Covance will use "[c]ommercially reasonable efforts . . . to facilitate the transfer of data by e-Trials including topography . . . to the data management vendor designated by the Company." The Master states that notices go to Mary Westrick at Covance.

I think all we need to do is indicate that MDS is one of the vendors we designate to receive the information. Do you agree?

-----Original Message-----

**From:** Carchman, Loreen  
**Sent:** Wednesday, October 30, 2002 12:38 PM  
**To:** Osborne, Kevin (PMMC Legal); Arnold, Amy  
**Cc:** Venable-Waple, Bristow (RD &E)  
**Subject:** FW: FW: Lab data specifications

Kevin/Amy,

Is this OK from a Legal perspective??? Thoughts???

Thanks,  
-L

-----Original Message-----

**From:** Roethig, Hans  
**Sent:** Tuesday, October 22, 2002 5:59 PM  
**To:** King, Valerie A.  
**Cc:** Carchman, Loreen; Venable-Waple, Bristow (RD &E); Oey, Jan  
**Subject:** RE: FW: Lab data specifications

I share your view!  
Perhaps Bristow my draft a letter when she is back.  
Best regards  
*Hans*

-----Original Message-----

**From:** King, Valerie A.  
**Sent:** Tuesday, October 22, 2002 10:55 AM  
**To:** Roethig, Hans  
**Subject:** FW: FW: Lab data specifications

Hans:

Please see Jeff Milhone's note below. I believe that is consistent with your thinking.

If you agree, I think it would be most appropriate if the communication he references should come from you. Let me know your thoughts.

Thanks,  
Valerie

-----Original Message-----

**From:** Jeffrey Milhone [SMTP:jeffrey.milhone@covance.com]  
**Sent:** Tuesday, October 22, 2002 10:18 AM  
**To:** Jill Schultz; Valerie.A.King@pmusa.com  
**Cc:** jaredfreedberg@covance.com  
**Subject:** Re: FW: Lab data specifications

It is my understanding that the scope of work for eTrials has not changed from what was first envisioned as they are merely transferring the data to MDS instead of Covance. The work that eTrials is doing is based on an approved subcontract and is ultimately covered as our subcontractor under Covance's agreement with Philip Morris. I believe all we need is something in writing from Philip Morris, a letter or formal email should suffice, referencing our contract and stating that we are authorized to share the information in question with MDS.

If you have any further concerns or wish to discuss it in more detail please feel free to contact me at (608) 242-2712 x2261.

>>> Jill Schultz 10/21/02 07:53PM >>>

Hi Valerie,

Just catching up on a few emails while I'm still away. I think a confidentiality agreement between etrials and MDS would be appropriate but there is no need for Master Agreement or Task Order.

Jeff, do you agree?

Jill

>>> <Valerie.A.King@pmusa.com> 10/18/02 01:30PM >>>

Hi Jill...I hope this finds you well after a great vacation.

I just wanted to follow-up with you on Hans' note below. I have been in discussions with the VP of contracts at MDS re the issue below. Hans was

under the impression that neither a confidentiality agreement nor a contract would need to be established between etrials and MDS. I need to find out if

this is a correct understanding based on the existing agreement between etrials and Covance. Please let me know so that I can get back to MDS as

soon as possible.

Thanks,  
Valerie

> -----Original Message-----

> From:Roethig, Hans  
> Sent:Wednesday, October 16, 2002 5:29 PM  
> To:'Jodi Pickering'; Steven.Zweig@mdsps.com ; Jill Schultz (E-mail)  
> Cc:Dana Winsted; Anthony.Cavaliere@mdsps.com ; Bob.Lynch@mdsps.com ;  
> Fang.Fan@mdsps.com ; kimberly.prchal@mdsps.com ; Robert.Earl@mdsps.com  
>

> Nelson, Bettie L; Adams, Candace R.; Roethig, Hans; Oey, Jan; Sarkar,  
> Mohamadi; Kinser, Robin D.; Feng, Shixia; King, Valerie A.  
> Subject: RE: Lab data specifications  
>  
> There must be some misunderstanding jodi, please talk to Jill Schultz  
from  
> Covance. I do not think that any new agreement is necessary between  
> e-trials and MDS. Your Covance agreement should cover these points.  
> Best regards  
> Hans J Roethig, MD, PhD, FCP, FFPM  
> Director Clinical Evaluation  
> Philip Morris USA  
> 615 Maury Street  
> Richmond, VA 23224  
> Phone: (804) 274-3165  
> Fax: (804) 274-2891  
> Mobile phone: (804) 687-1655  
> e-mail: hans-juergen.roethig@PMUSA.com  
>  
> -----Original Message-----  
> From: Jodi Pickering [mailto:jodi.pickering@etrials.com]  
> Sent: Monday, October 14, 2002 10:55 AM  
> To: Steven.Zweig@mdsps.com  
> Cc: Dana Winsted; Anthony.Cavaliere@mdsps.com ; Bob.Lynch@mdsps.com ;  
> Fang.Fan@mdsps.com ; kimberly.prchal@mdsps.com ; Robert.Earl@mdsps.com  
> ;  
> bettie.l.nelson@pmusa.com ; candace.r.adams@pmusa.com ;  
> Hans-Juergen.Roethig@pmusa.com ; Jan.Oey@pmusa.com ;  
> mohamadi.sarkar@pmusa.com ; robin.d.kinser@pmusa.com ;  
> Shixia.Feng@pmusa.com ; Valerie.A.King@pmusa.com  
> Subject: RE: Lab data specifications  
>  
>  
> Steven,  
>  
> As discussed, we will need to have at a minimum a Confidentiality  
> Agreement in place prior to any information being transferred between  
MDS  
> and etrials. We also will need a Master Services Agreement as well as  
a  
> Task Order to accommodate for the transfer fees and the final database  
  
> transfer to MDS. Please feel free to call me to discuss this further.  
>  
> Best regards,  
>  
> Jodi Pickering  
> > etrials, Inc  
> > Contracts Management and Proposal Development  
> 919.653.2067  
> 919.653.2001 (fax)  
>  
>  
>  
> -----Original Message-----  
> From: Steven.Zweig@mdsps.com [mailto:Steven.Zweig@mdsps.com]  
> Sent: Monday, October 14, 2002 10:05 AM  
> To: Jodi Pickering  
> Cc: Dana Winsted; Anthony.Cavaliere@mdsps.com ; Bob.Lynch@mdsps.com ;  
> Fang.Fan@mdsps.com ; kimberly.prchal@mdsps.com ; Robert.Earl@mdsps.com  
> ;  
> bettie.l.nelson@pmusa.com ; candace.r.adams@pmusa.com ;  
> Hans-Juergen.Roethig@pmusa.com ; Jan.Oey@pmusa.com ;  
> mohamadi.sarkar@pmusa.com ; robin.d.kinser@pmusa.com ;

> Shixia.Feng@pmusa.com ; Valerie.A.King@pmusa.com  
> Subject: Lab data specifications  
>  
>  
>  
> Jody,  
>  
> The ID variable specifications will need to be consistent across all  
data  
> sources.  
>  
> Can you please provide ID variable specifications for the etrials data  
  
> base. This would include name, type (number or character), and  
structure  
> for the investigator, patient, and visit variables.  
>  
> Thanks much,  
> Steven  
>

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